DIA Learning

Online Learning Opportunities

Continuing Education

DIA's Continuing Education program has been approved by a wide range of leading accrediting bodies that oversee the awarding of continuing education credits.

DIA is accredited by the **Accreditation Council for Pharmacy Education (ACPE)** as a provider of continuing pharmacy education.

DIA has been accredited as an Authorized Provider by the **International Association for Continuing Education and Training (IACET)**.

Continuing Education credits are offered for some eLearning modules.
Visit **DIAglobal.org/CE** for more details on Continuing Education and DIA's Disclosure Policy.

DIA has been reviewed and approved as a provider of project management training by the Project Management Institute (PMI).

Customized Onsite Training Solutions

Bring these courses to your colleagues.

DIA can tailor any training course or curriculum specifically for your team, department, or entire organizaton.

DIA is recognized throughout the life sciences community as the definitive source for information about the discovery, development, and life cycle management of pharmaceuticals, biotechnology, and related health care industries. Top companies around the world trust DIA to deliver current, relevant, and effective education and professional onsite training.

Let us bring the perfect customized training experience to you!

Exclusive benefits of our onsite training program include:

- Expert training from professionals in the life sciences arena
- Quality content delivered to your organization's location, saving time and cost
- Courses tailored to meet your specific training objectives
- Continuing education credits

For more information contact
Heej.Ko@diaglobal.org or visit **DIAglobal.org/Onsite** to submit a consultation request.

Clinical Research

ART OF WRITING A CLINICAL OVERVIEW

This online course provides an in-depth analysis of the preparation of a Clinical Overview for pharmaceutical products (drugs and biologics) in accordance with ICH guidelines concerning development of Module 2.5 of a Common Technical Document (CTD).

Featured Topics:

- Objectives, Structure, and Format of the Clinical Overview, with Attention Given to Developing a Document Suitable for Multi-region Submissions
- Inclusion and Presentation of Clinical and Nonclinical Data, with Emphasis on how to Effectively Use the Other Technical Summaries Within the CTD
- Preparing a Document that Successfully Communicates the Benefits and Risks of the Investigational Product
- Framing the Different Sections of the Clinical Overview to Best Communicate the Product's Unique Attributes
- Identifying How to Develop the Clinical Overview for Other Types of Submissions

Online Course Level: Beginner Online Course Duration: 6 hours

CLINICAL STATISTICS FOR NONSTATISTICIANS

Answer common questions and address topics such as confidence intervals, hypothesis testing, trial designs, and methods for establishing noninferiority. This course will increase the level of statistical knowledge of nonstatisticians so collaborative efforts of statisticians and nonstatisticians on clinical investigative teams can be improved.

Featured Topics:

- Basic Statistical Concepts Relevant to Clinical Research
- Introductory Statistics
- Limited Use Computational Formulas
- How to Critically Think About Data, Making Valid Inferences, and Understanding How Statisticians are an Essential Element of Clinical Investigations

Online Course Level: Beginner Online Course Duration: 8 hours 30 minutes

Clinical Research

To purchase, visit
DIAglobal.org/clinical-trials

Group Rates and Licensing information on page 16.

CLINICAL TRIAL FUNDAMENTALS eLEARNING PROGRAM

The Clinical Trial Fundamentals eLearning Program is designed to provide a practical context to help clinical research professionals learn about conducting clinical trials. Using an interactive case study with realistic scenarios designed to illustrate the learning points, the program follows the activities of a fictitious clinical investigator and her staff as they prepare for, initiate, and conduct a clinical study. As learners make decisions during the clinical trial, the program illustrates how clinical trial regulations and guidelines impact each situation, and the complex details of clinical trial study management.

The eLearning program includes three self-paced modules that can be accessed anytime, anywhere. Users will have one year to complete the modules and continuing education credits are offered. Additionally, this ICH E6 GCP Investigator Site Training meets the Minimum Criteria for ICH GCP Investigator Site Personnel Training identified by TransCelerate BioPharma Inc., as necessary to enable mutual recognition of GCP training among trial sponsors.

Clinical Trials: Study Preparation

Featured Topics:

- Responsibilities of the Investigator and Sponsor
- Study Documents
- Clinical Trial Phases
- Study Design
- Use of Placebo
- International Conference on Harmonisation
- Drug Development Legislation
- Ethical Considerations in Clinical Research
- Responsibilities of the Study Staff
- The Site Evaluation Visit
- The Study Budget
- The Contract

Clinical Trials: Study Initiation

Featured Topics:

- FDA Form 1572
- Financial Disclosure
- Institutional Review Board
- Informed Consent and HIPAA
- Study Initiation Documents
- The Investigator Meeting
- The Study Initiation Meeting
- Investigator Study Files

Clinical Trials: Conducting the Study

Featured Topics:

- Subject Recruitment, Selection, Retention, and Compliance
- Applying the Informed Consent Process During a Clinical Trial
- Classifying, Recording, and Reporting Adverse Events
- Managing Monitoring Visits
- FDA Inspections
- Post-Study Critique and Study Closure

Clinical Research

DEVELOPMENT OF A CLINICAL STUDY REPORT

This course is designed for professionals new to clinical development and Clinical Study Report preparation. The Clinical Study Reports for submission to the Health Authorities are required to be in compliance with the International Conference on Harmonisation (ICH) standards and must meet high-quality standards so it provides the most concise yet comprehensive summary of the study. The course will provide latest strategies for preparing such clear, well organized, ICH-compliant Clinical Study Reports in the most efficient way.

Featured Topics:

- Structure and Format of a Clinical Study Report in Accordance with ICH Guidelines
- Investigational Plans Using Statistical Methodology
- Study Population and Protocol Deviations
- Placement and Presentation of Study Information and Data in Various Report Sections Including Tables, Appendices, and Supporting Documentation
- Safety and Efficacy Results
- Pharmacokinetic and/or Pharmacodynamic Endpoints
- Acceptability of Abbreviated Study Reports

Online Course Level: Beginner Online Course Duration: 5 hours 30 minutes

Clinical Trial Management Comprehensive eLearning Bundle

This eLearning bundle includes the Clinical Trial Fundamentals eLearning Program and the Informed Consent: Comprehensive Concepts and Components module. The self-paced courses are mobile compatible and learners will have access for one full year to complete them. Learning at your fingertips anywhere, anytime, and at a time that works for you!

Featured Topics:

- Responsibilities of the investigator and sponsor
- Elements of Informed Consent and HIPAA
- eConsent
- Responsibilities of the study staff
- Managing monitoring visits

Flexibility to Learn Anywhere, Anytime - at Your Own Pace

INFORMED CONSENT: COMPREHENSIVE CONCEPTS AND COMPONENTS

This comprehensive eLearning module provides the key concepts of informed consent. It explains the components of a complete and appropriate consent form as specified by the International Conference on Harmonisation (ICH) and the US FDA, as well as guidance for the creation and appropriate wording of these components. It also includes a discussion on the benefits and concerns with electronic informed consent, and presents publications and projects that explore the use of eConsent.

Featured Topics:

- Determining When Informed Consent Is Necessary
- Comprehension Guidelines
- Overview of Elements of Consent
- Writing the Introduction and Purpose Statement
- Contact Information, Consent Statements, and Signatures
- Long Form versus Short Form, and Tips for Administering Consent
- Changes to Informed Consent Under HIPAA

INNOVATIVE STATISTICAL APPROACHES FOR CLINICAL TRIALS

This online training course will increase the level of statistical knowledge of nonstatisticians so collaborative efforts of statisticians and nonstatisticians on clinical investigative teams can be improved.

Featured Topics:

- Statistics to Make Better Decisions in the Drug Development Process
- Statistical Models
- Trial Design and Management
- Multiplicity Adjustments
- Clinical Equivalence
- Noninferiority Clinical Trial Designs
- Basics of Bayesian Methods
- Survival Trials

Online Course Level: Intermediate-advanced Online Course Duration: 7 hours 30 minutes

OVERSIGHT OF CLINICAL MONITORING AND STRATEGIES

Hear from experienced faculty on the trends impacting monitors, requirements, approaches, selection, and how to manage a site monitor's performance. This course also focuses on the elements of risk-based monitoring.

Featured Topics:

- Trends in the Clinical Development Landscape Driving Change in ICH and FDA Requirements for Site Monitoring
- Current Approaches to Risk-Based Monitoring
- Warning Signs and Problems with Site Monitors
- Managing Site Monitors and Their Performance
- Common Errors Made in Site Monitoring
- Metrics Used to Measure Site Monitor Performance

Online Course Level: Intermediate Online Course Duration: 6 hours

PREPARING A CLINICAL TRIAL BUDGET

Learn how to prepare a high-level estimate of a clinical trial budget. You will walk through practical examples of estimating a clinical trial budget and the assumptions associated with each.

Featured Topics:

- Identifying Cost Triggers in a Clinical Trial
- How to Estimate Investigator Fees
- Budgeting Tips and Tricks
- How to Estimate CRO Costs
- How to Estimate Consulting Fees

Online Course Level: Intermediate Online Course Duration: 1 hour 30 minutes

What Our Customers Are Saying...

"This was the single most relevant and applicable training I have done thus far."

Clinical Safety and Pharmacovigilance

DRUG SAFETY eLEARNING PROGRAM

Drug safety is a primary concern throughout the health care product development life cycle. To help organizations address the challenges and ensure compliance with regulations, DIA developed an in-depth six module Drug Safety eLearning Program to provide the knowledge you and your staff need.

Introduction to Drug Safety

Get information on the legal basis for safety reporting, including a historical perspective; basic definitions and tools; the mechanics of drug safety and pharmacovigilance; reference safety information provided by the Investigator's Brochure and postmarketing labeling; and evaluation of seriousness, expectedness, and causality.

Featured Topics:

- The Basics of Drug Safety
- Terminology
- A "Typical" Company Safety Unit
- Tracking a Case from Start to Finish
- Assessing Cases
- Reference Safety Information: The Investigator Brochure and Postmarketing Labeling

Drug Safety Regulatory Requirements

This module includes harmonization initiatives, key US and EU regulations, the roles that ICH and CIOMS play in drug safety regulations, good clinical and pharmacovigilance practices, and standard operating procedures (SOPs) that support drug safety.

Featured Topics:

- Harmonization Initiatives
- Important US Regulations
- Important EU Regulations
- Good Clinical and Pharmacovigilance Practices
- Standard Operating Procedures

Premarketing Clinical Trial Safety

Get information about safety and ethical safeguards in place to protect human subjects in clinical trials: informed consent, institutional review boards and ethics committees, data safety monitoring boards, and more.

Featured Topics:

- Informed Consent
- Institutional Review Board/Ethics Committee
- Individual Case Reporting
- Aggregate Reporting
- Risk Assessment
- Premarketing Review of Safety Data in an Application
- Data and Safety Monitoring Boards

To purchase, visit
DIAglobal.org/safetyelearning

Group Rates and Licensing information on page 16.

Postmarketing Safety Management

Get the framework and details around drug safety monitoring requirements for drugs after they are approved for marketing. This module provides information about spontaneous reporting, aggregate reporting, risk assessment, benefit-risk management, risk management plans, and risk evaluation and mitigation strategies (REMS).

Featured Topics:

- Spontaneous Case Reporting
- Aggregate Reporting
- Benefit-risk Assessment
- Risk Management Plans
- Risk Evaluation and Mitigation Strategies
- Postmarketing Case Studies

Basics of Signal Detection and Pharmacoepidemiology

Get an introduction to signal detection in pharmacovigilance. This module covers safety signal basics, safety databases, data mining and the mathematics of drug safety, principles of pharmacoepidemiology, and signaling regulations.

Featured Topics:

- Safety Signal Basics and Regulations
- Safety Databases
- Pharmacoepidemiology

Safety Audits and Inspections

Get an overview about audits and inspections, with specific focus on the US FDA, European Medicines Agency (EMA), and the UK's Medicines and Healthcare Products Regulatory Agency (MHRA) inspections. This module also discusses common inspection findings, how companies should respond to an inspection, and practicalities of inspections and audits.

Featured Topics:

- Types and Scope of Audits and Inspections
- Common Inspection Findings
- Responding to an Inspection
- Corrective and Preventative Action Plan

Drug Safety

HOW TO PREPARE FOR A SAFETY INSPECTION

Every pharmacovigilance department will, at one time or another, undergo a governmental or health authority inspection as well as audits by vendors, partners, suppliers, internal auditors, and others. This online training course will teach you how to prepare for an audit/inspection from the time of the receipt of the announcement (or of the arrival of the inspectors at your doorstep) to conclusion of the audit.

Featured Topics:

- Different Types of Inspections and Audits from Around the World (EMA, UK MHRA, and US FDA)
- How to Prepare for an Audit/Inspection
- How to Prepare a Response and Corrective Action Plans
- Review Case Studies

Online Course Level: Beginner Online Course Duration: 5 hours

INTRODUCTION TO SIGNAL DETECTION AND DATA MINING

This online training reviews approaches to the implementation of signal detection and data mining as part of your pharmacovigilance operations. Topics discussed will include signal identification and assessment, application of available regulatory guidance documents, review of data visualization tools to facilitate signal detection and evaluation, and the use of EU GVP Module IX to structure and organize a signal management process.

Featured Topics:

- Why Signal Detection is Needed
- Regulatory Requirements
- Approaches to Signal Detection
- Good Pharmacovigilance Practices
- Data Mining Fundamentals
- Introduction to the Bayesian Confidence Propagation Neural Network (BCPNN)
- Proportional Reporting Ratio (PRR)
- Multi-Item Gamma Poisson Shrinker (MGPS)
- Signal Detection Strengthening and Management
- Signal Detection Process and Operation
- Risk Management Basics in the US and the EU

Online Course Level: Beginner Online Course Duration: 6 hours

Flexibility to Learn Anywhere, Anytime - at Your Own Pace

The Essentials

DRUG DEVELOPMENT AND LIFE CYCLE MANAGEMENT eLEARNING PROGRAM

DIA's six module Drug Development and Life Cycle Management eLearning Program will help you understand how organizations structure their efforts and utilize their resources to improve the odds of successful development, and potentially minimize the risks associated with shepherding a new drug candidate through the development process.

Overview of Drug Development

This module provides a high-level overview of the breadth of activities required to move a potential drug candidate from idea to the marketplace, with an emphasis on how various functional areas contribute at each stage of development, and how they are organized. It also discusses the regulatory environment in which these activities occur.

Featured Topics:

- Phases of Drug Development
- Drug Development Regulations
- Workflow for Bringing a New Drug to Market
- Functional Areas Involved in the Drug Development Process

Discovery and Preclinical Testing Phases

Focus on how companies advance potential drug candidates through the earliest stages of research, from therapeutic target to readiness for clinical studies.

Featured Topics:

- Discovery Activities
- Toxicology Studies
- Use of Biomarkers and Surrogate Markers
- Drug Substance Production and Drug Product Formulation Activities
- Good Manufacturing and Laboratory Practices

Phase 1 Studies

This module will take you through the activities associated with Phase 1 development, with a focus on the drivers impacting design of the First in Human study.

Featured Topics:

- Objectives of Phase 1 Studies
- Regulatory Submissions Required for Phase 1 Studies
- Key Activities that Need to be Completed Before First in Human Clinical Trials can Begin
- Risk-Return Decisions Involved in Phase 1 Studies

Phase 2 Studies

Explore the factors that drive the design and conduct of Phase 2 clinical trials, as well as the activities and functional areas that contribute to a successful Phase 2 program.

Featured Topics:

- Key Objectives and Activities of Phase 2 Studies
- Risk-Return Decisions Involved in Phase 2 Studies
- Regulatory Activities and Decisions that Occur During Phase 2 Studies

Phase 3 Studies and Regulatory Review

Gain an understanding of what clinical study activities occur during Phase 3 studies, and the regulatory requirements for and components of an application for marketing approval in the US and EU.

Featured Topics:

- Clinical Study Activities of Phase 3 Studies
- Safety Reporting Requirements
- Regulatory Review Process in the US and EU
- Components of the CTD

Phase 4 and Life Cycle Management

This modules reviews typical activities associated with management of a marketed drug, as well as focus on how companies maximize the value of approved products through the life cycle management process.

Featured Topics:

- Key Objectives of Phase 4 Studies
- Five Stages of a Product Life Cycle
- How to Grow or Maintain Market Share by Capitalizing on Product or Patient Characteristics

OVERVIEW OF DRUG DEVELOPMENT IN JAPAN

Learn proven strategies for minimizing your drug development regulatory challenges in the US and Japan.

Featured Topics:

- The Japanese Regulatory Authority: Organization and Key Processes
- Requirements for Successful Drug Development in Japan
- How the Culture in Japan Impacts Business Relations and Communication
- Real-World Experiences of Drug Development in Japan

Online Course Level: Beginner Online Course Duration: 6 hours

Medical Communications

MEDICAL COMMUNICATIONS eLEARNING PROGRAM

DIA's Medical Communications eLearning Program includes eight modules, covering key medical communication or information principles. Each module contains relevant examples or scenarios designed to simulate medical information related tasks, so learners can apply the concepts to their day-to-day job responsibilities. The core topics covered include literature searching and evaluation, handling medical inquiries, writing medical responses, compliance, understanding study designs and statistics, product labeling, and crisis management. The online program is self-paced and can be accessed anytime, anywhere. Users will have one year to complete the modules and continuing education credits are offered.

Literature Searching

This module is designed to help medical affairs professionals search for medical literature in order to satisfy requests for information from consumers, external health care professionals, and internal colleagues. It contains current resources and the latest search strategies compiled by industry experts. This practical and useful information can be immediately applied to your daily work in medical affairs.

Featured Topics:

- Identifying, Assessing, and Clarifying Inquiries
- Developing a Search Strategy
- Selecting Literature Databases
- Refining Results and Finalizing an Inquiry
- Sources of Published References
- Copyright Considerations

Literature Evaluation

This module is designed to help medical affairs professionals effectively evaluate scientific literature so they can identify and provide relevant and reliable information to health care professionals regarding the use of a particular drug.

Featured Topics:

- Study Design and Controls
- Measuring Study Results
- Describing the Data
- Presenting and Interpreting the Results
- Establishing Causality
- Determining Importance and Generalizability of Results

Database Management and Medical Inquiries

This module provides medical affairs professionals with an overview of the utility and application of database management systems in the Medical Communications or Information Department. It will also assist in fielding questions, retrieving information, and delivering responses verbally.

Featured Topics:

- Using a Database for Information Management
- Receiving and a Responding to Request for Medical Information
- Types of Responses

Medical Response Excellence

This module familiarizes medical affairs professionals with the preparation of written responses to specific drug information questions.

Featured Topics:

- Regulatory Guidelines
- Writing Tips and Recommendations
- Anatomy of a Complete Written Response
- Writing and Editing an Abstract

Medical Communications

To purchase, visit
DIAglobal.org/MedComm-eLearning

Group Rates and Licensing information on page 16.

Statistics For Medical Affairs

This module is designed to help evaluate statistical data presented in medical literature. It will help users to apply statistical concepts when evaluating literature, identify strengths and weaknesses in study design, and detect potential bias in the presentation of statistics.

Featured Topics:

- Statistical Concepts
- Basic Statistics
- Hypothesis Testing
- Study Designs

US Regulatory and Compliance Considerations

This module will help to understand and comply with regulations and guidances around the dissemination of information about drug products. It focuses on the United States FDA and its regulations.

Featured Topics:

- FDA Regulatory Standards for Advertising and Promotional Labeling
- Requirements for Advertising and Promotional Labeling
- Special Types of Advertising and Promotional Events
- Promotion Versus Scientific Exchange
- The On-Label and Off-Label Controversy
- Direct-To-Consumer Promotion
- Compliance

Crisis Management

This module provides medical affairs professionals with an overview of crisis management. It gives a brief background on product recalls and associated regulations. An emphasis is placed upon the actions needed to prepare for and successfully manage a crisis.

Featured Topics:

- Types of Crisis Situations
- Crisis Impacts and Recalls
- Contingency Planning
- Actions in Managing a Crisis

Product Labeling

This module explains the need for, and definition of, labeling for prescription drugs and biologic products. It discusses how labeling is developed and maintained throughout the product's marketed life, the components and structure of prescription drug and biological product labeling, and pertinent regulatory and legal requirements with which they must comply.

Featured Topics:

- Global Labeling: The Company Core Data Sheet
- Labeling in the US: Prescribing Information and the Medication Guide
- Labeling in the European Union: The Summary of Product Characteristics
- Labeling in Non-US and Non-EU Countries
- Maintenance of Product Labeling

Group Rates and Licensing!

DIA offers group rates to companies interested in purchasing eLearning modules for 10+ users! To request a proposal for multiple users, contact eLearning@DIAglobal.org.

Project Management

PREPARING A CLINICAL TRIAL BUDGET

This online training course will teach you how to prepare a high-level estimate of a clinical trial budget. You will walk through practical examples of estimating a clinical trial budget and the assumptions associated with each.

Featured Topics:

- How to Identify Cost Triggers in a Clinical Trial
- How to Estimate Investigator Fees
- Budgeting Tips and Tricks
- How to Estimate CRO Costs
- How to Estimate Consulting Fees

Online Course Level: Intermediate Online Course Duration: 1 hour 30 minutes

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Regulatory Affairs

BASICS OF THE IND PHASE

Discuss FDA regulations and expectations for the content, submission, and review of Investigational New Drug (IND) Products and the importance of regulatory strategy. The course focuses on prescription drug and well characterized biological products.

Featured Topics:

- Fundamentals of Investigational New Drug Products
- Activities and Submissions Required to Maintain an IND
- Special Regulatory Considerations for Clinical Development

Online Course Level: Beginner Online Course Duration: 6 hours 45 minutes

BASICS OF THE NDA PHASE

This training will discuss the aspects of New Drug Application (NDA) preparation. The course focuses on drug and well characterized biological products.

Featured Topics:

- Practical Steps Required to Prepare an NDA
- Postapproval Activities

Online Course Level: Beginner Online Course Duration: 6 hours

INTERACTIONS WITH THE FDA DURING IND/NDA PHASES

Explore the various methods for communicating with the FDA, including telephone calls, emails, faxes, and meetings. Special attention is given to the types of formal FDA meetings available to industry, as well as specific details on how and when to request them. Finally, you will receive specific recommendations, based on the experience of leading regulatory affairs professionals, on how to conduct successful and productive meetings with FDA.

Featured Topics:

- FDA's Guidance on Meetings
- Time Course of Events in Requesting a Meeting
- Objectives and Conduct of Specific Meetings with FDA
- Principles for Communicating with FDA
- Meeting Etiquette
- How to Resolve Issues or Disputes with FDA
- Summary on Interacting in FDA Advisory Committee Meetings

Online Course Level: Beginner Online Course Duration: 2 hours

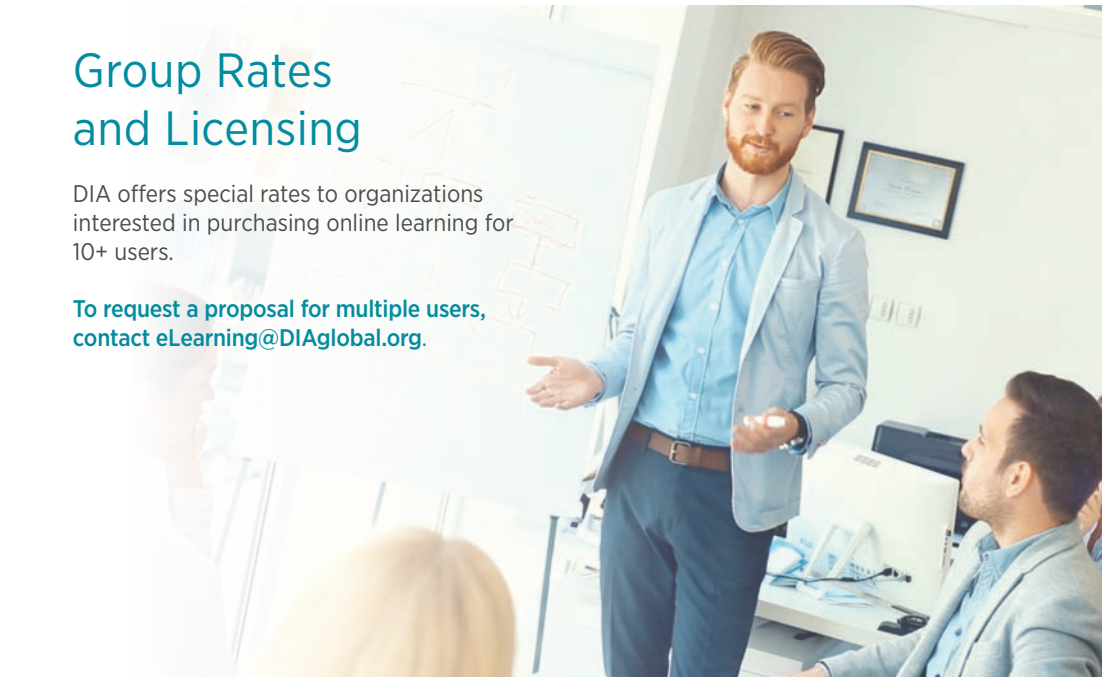
REGULATORY ASPECTS OF PRESCRIPTION DRUG/BIOLOGICS ADVERTISING AND PROMOTIONAL LABELING

This course will provide you with the fundamentals of FDA regulations and guidances related to prescription drug advertising and promotional labeling. You will learn how to apply this information when you serve as a Regulatory representative for promotional review committees that assess traditional and newer forms of promotional materials for compliance. The course will also provide you with the information you need to ensure that other related pharmaceutical industry activities are conducted appropriately, and are not regarded as violative promotion.

Featured Topics:

- Statutory Basis for Promotional Regulations
- Required Elements for Advertisements and Promotional Labeling
- Reminder Advertisements/Labeling
- Preapproval Promotional Activities
- FDA Enforcement Actions
- Launch Promotional Pieces
- Postmarketing Submissions of Advertising

Online Course Level: Beginner Online Course Duration: 2 hours



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